

animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

(b) The definitions of the following terms are given in §514.3 of this chapter:

Adverse drug experience.

Product defect/manufacturing defect.

Serious adverse drug experience.

Unexpected adverse drug experience.

(c) The definitions of the following terms are given in §516.3 of this chapter:

Same dosage form.

Same drug.

Same intended use.

**§516.117 Submission of correspondence under this subpart.**

Unless directed otherwise by FDA, all correspondence relating to any aspect of the new animal drug indexing process described in this subpart must be addressed to the Director, OMUMS. The initial correspondence for a particular index listing should include the name and address of the authorized contact person. Notifications of changes in such person or changes of address of such person should be provided in a timely manner.

**§516.119 Permanent-resident U.S. agent for foreign requestors and holders.**

Every foreign requestor and holder shall name a permanent resident of the United States as their agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the requestor or holder. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent resident U.S. agent may be an individual, firm, or domestic corporation and may represent any number of requestors or holders. The name and address of the permanent-resident U.S. agent shall be submitted to the Director, OMUMS, and included in the index file.

**§516.121 Meetings.**

(a) A requestor or potential requestor is entitled to one or more meetings to

discuss the requirements for indexing a new animal drug.

(b) Requests for such meetings should be in writing, be addressed to the Director, OMUMS, specify the participants attending on behalf of the requestor or potential requestor, and contain a proposed agenda for the meeting.

(c) Within 30 days of receiving a request for a meeting, FDA will attempt to schedule the meeting at a time agreeable to both FDA and the person making the request.

**§516.123 Informal conferences regarding agency administrative actions.**

(a) Should FDA make an initial decision denying a request for determination of eligibility for indexing, terminating an investigational exemption, determining that a qualified expert panel does not meet the selection criteria, denying a request for addition to the index, or removing a new animal drug from the index, FDA will give written notice that specifies the grounds for the initial decision and provides an opportunity for an informal conference for review of the decision.

(b) The written notice will include information for scheduling the informal conference and state that a written request for a conference must be made within 60 days of the date FDA sends its notice.

(c) Within 45 days of receiving a request for an informal conference, FDA will schedule and hold the informal conference at a time agreeable to both FDA and the person making the request.

(d) Such an informal conference will be conducted by a presiding officer who will be the Director of the Center for Veterinary Medicine or his or her designee, excluding the Director of the Office of Minor Use and Minor Species Animal Drug Development and other persons significantly involved in the initial decision.

(e) The person requesting an informal conference must provide a written response to FDA's initial decision at least 2 weeks prior to the date of the scheduled meeting. Generally, this written response would be attached to the request for an informal conference.

At the option of the person requesting an informal conference, such written response to FDA's initial decision may act in lieu of a face-to-face meeting. In this case, the informal conference will consist of a review by the presiding officer of the submitted written response.

(f) The purpose of an informal conference is to discuss scientific and factual issues. It will involve a discussion of FDA's initial decision and any written response to that decision.

(g) Internal agency review of a decision must be based on the information in the administrative file. If the person requesting an informal conference presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

(h) Informal conferences under this part are not subject to the separation of functions rules in §10.55 of this chapter.

(i) The rules of evidence do not apply to informal conferences. No motions or objections relating to the admissibility of information and views will be made or considered, but any party to the conference may comment upon or rebut all such data, information and views.

(j) [Reserved]

(k) The presiding officer will prepare a written report regarding the subject of the informal conference that states and describes the basis for his or her findings. Whenever time permits, the parties to the informal conference will have 30 days to review and comment on the report.

(1) The administrative record of the informal conference will consist of:

(1) The notice providing an opportunity for an informal conference and the written response to the notice.

(2) All written information and views submitted to the presiding officer at the conference or, at the discretion of the presiding officer, thereafter.

(3) The presiding officer's written report.

(4) All correspondence and memoranda of any and all meetings between the participants and the presiding officer.

(m) The administrative record of the informal conference is closed to the

submission of information at the close of the conference, unless the presiding officer specifically permits additional time for further submission.

(n) The administrative record of the informal conference specified herein constitutes the exclusive record for decision.

**§516.125 Investigational use of minor species new animal drugs to support indexing.**

(a) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug intended solely for investigational use in minor species shall meet the requirements of part 511 of this chapter if the investigational use is for the purpose of:

(1) Demonstrating human food safety under section 572(a)(1)(B) of the act;

(2) Demonstrating safety with respect to individuals exposed to the new animal drug through its manufacture and use under section 572(c)(1)(F) of the act;

(3) Conducting an environmental assessment under section 572(c)(1)(E) of the act; or

(4) Obtaining approval of a new animal drug application or abbreviated new animal drug application under section 512(b) of the act.

(b) Correspondence and information associated with investigations described in paragraph (a) of this section shall not be sent to the Director, OMUMS, but shall be submitted to FDA in accordance with the provisions of part 511 of this chapter.

(c) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug intended solely for investigational use in minor species, other than for an investigational use described in paragraph (a) of this section, shall meet the requirements of this section. For such investigations, all provisions of part 511 of this chapter apply with the following modifications:

(1) Under §511.1(a)(1) of this chapter, the label statement is as follows:

“*Caution.* Contains a new animal drug for investigational use only in laboratory animals or for tests in vitro in support of index listing. Not for use in humans.”